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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,352	11/02/2006	Toshikazu Ushijima	Q93839	1137
23373 7590 11/14/2008				
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SUITE 800				
WASHINGTON, DC 20037				
EXAMINER				
WHISENANT, ETHAN C				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
11/14/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/572,352

**Applicant(s)**

USHIJIMA ET AL.

**Examiner**

Ethan Whisenant

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.  
4a) Of the above claim(s) 20-27 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-8, 10, 12-14 and 16-19 is/are rejected.  
7) ☒ Claim(s) 9, 11 and 15 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 16 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 16 MAR 08  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**NON-FINAL ACTION**

1. The applicant's election of Group I (**Claims 1-19**) with traverse in the paper(s) filed 26 SEP 08 is acknowledged. Claims 20-27 are withdrawn from further consideration as being directed toward a non-elected invention.

The traversal of the restriction requirement is based on the applicant's contention that the special technical feature linking the claims is the link between the methylation frequency of Fibrillin2 gene, its level of expression and link to cancer. The applicant's argument has been fully considered but is not deemed to be persuasive. It is noted that the special technical feature recited (i.e. the claim limitation) above is not present in Groups III, IV or V. Because the restriction requirement is deemed proper it is herein made **FINAL**.

**SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

**35 USC § 112 - 1ST PARAGRAPH**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH**

**4. Claim(s) 1-8, 10, 12-14 and 16-19** is/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the methylation frequency of Fibrillin 2 gene (i.e. FBN2) in order to diagnose/detect pancreatic cancer does not reasonably provide enablement for each and every type of cancer (i.e. cancerous state). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, the scope of the claim encompasses measuring /determining the methylation status of the FBN2 gene in order to diagnose/detect all types of cancer (i.e. cancerous states) in all known organisms. The application only teaches determining the methylation status of the FBN2 gene in human pancreatic cancers (i.e. human pancreatic cancer cell lines). There is no evidenced that the FBN2 gene is hypermethylated or hypomethylated in other types of cancer/cancer cell lines. As regards the state of the prior art, many genes have been found to have aberrant methylation in cancerous tissues (including pancreatic cancers). Neither is there evidence presented that aberrant methylation of the FBN2 gene is a universal marker of cancer. Hypermethylation is often associated with decrease expression of the hypermethylated gene in said cancerous tissues while hypomethylation has been associated with increased expression of the hypomethylated gene in cancerous tissues.

As regards the prior art, there is no teaching in the prior art regarding the methylation status of the FBN2 gene in any cancers. It would be relatively simple to examine other cancers for their methylation status of the FBN2 gene, however, there are hundreds of different cancers in humans alone. All of the working examples relate to human pancreatic cancer (i.e. human pancreatic cancer cell lines). Accordingly, it is concluded that undue experimentation is required to practice the full scope of the invention as it is claimed.

#### **CLAIM OBJECTIONS**

5. **Claim(s) 9, 11 and 15** is /are objected to as being dependent upon a rejected base claim, would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action.

#### **CONCLUSION**

6. **Claim(s) 1-19** is/are rejected and/or objected to for the reason(s) set forth above.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

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The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/  
Primary Examiner  
Art Unit 1634

## EXAMINER SEARCH NOTES

**09 NOV 08 - ECW**

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

STIC searched SEQ ID NO. 1

Inventor(s) : e.g. Ushijima T ?/au

Fibrillin 2 or Fibrillin2 or Fibrillin or FBN2

gene

methylation or methylated

canc\$

pancreas or pancreatic